Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0105229	08/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pilgrim Medical Center Inc	393 Bloomfield Avenue, Montclair, NJ	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for Total Beta-Human chorionic gonadotropin (hCG) tests from December 2022 to the date of survey. The TP confirmed on 8/2/23 at 1:40 pm the laboratory was not enrolled in PT for Total beta-hCG tests.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test

	system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to have work and attestation records for all American Associates of Bioanlalysts (AAB) PT events for Endocrinology, Immunology, Rhesus (Rh) factor, and Serology tests in the calendar years 2023, 2022 and 2021. The findings include: 1. There were no work or attestation records for all PT events in the calendar years 2023, 2022 and 2021 2. The TP confirmed on 8/2/23 at 1:35 pm work and attestation records were not available for PT events as mentioned above.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to have a procedure for Quality control verification (QVC) for Endocrinology, Immunology, Rhesus (Rh) factor, and Serology testing and six month correlation studies for Endocrinology testing from 6/08 /21 to the date of survey. The TP confirmed on 8/2/23 at 2:30 pm that the laboratory failed to have the above mentioned procedures.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the i-Stat Operators Manual (OM) and interview with the Testing Personnel (TP) the laboratory failed to OM From December 2023 to the date of survey. the findings include: 1) OM stating in "Quality Control" "daily procedures", "Verify the performance of each handheld in the i-STAT System using the internal or external Electronic Simulator every 24 hours of use," 2) There was no documented evidence the aforementioned procedure was performed. 3) The TP confirmed on 8/2/23 at 1:00 pm that the laboratory did not follow the OM.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to perform and document two levels of external controls on each day of patient testing for Total Beta-Human chorionic gonadotropin (hCG) run on the i-Stat analyzer from December 2022 to the date of the survey. The findings include: 1. The laboratory reported Total Beta-hCG results but there was no documented evidence that QC was performed every day of patient testing. 2. The laboratory performed approximately 4 Total Beta-hCG tests weekly. 3. The TP confirmed on 8/2/23 at 2:20 pm that two levels of QC were not run each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Endocrinology, Immunology, Rhesus (Rh) factor, and Serology tests performed on Abbott i-Stat, Wampole Impact RPR, Immuncor Rh, and ASI Rubella test systems on the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The TC confirmed on 8/2/23 at 2:20 pm that the QC material was not verified before putting in use.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual the lack of a correlation study and interview with the Testing Personnel (TP), the laboratory failed to perform correlation studies for Endocrinology tests performed on the i-Stat analyzers twice per year in the date of survey. The finding includes: 1. TP stated they "did not know a correlation study was needed" for instrument to instrument comparison of the two i-Stat analyzers. 2. The TP confirmed on 8/2/23 at 1:00 pm that the laboratory did not perform a correlation study twice a year.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 6/8/21 to the date of survey. The findings include: 1. The LD failed to ensure that Performance Specifications procedures were adequate. Cross refer 6013. 2. The LD failed to ensure that Proficiency Testing samples were tested. Cross refer 6016. 3. The LD failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. 4. The LD failed to failed to have appropriate education and training documentation on all TP. Cross refer 6029.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed for Total Protein tests performed on the Total Beta-Human chorionic gonadotropin (hCG) testing performed on the Abbott i-Stat analyzer were adequate from December 2022 to the date of survey. The findings include: 1. There was no documented evidence that linearity was performed on two out of two analyzers. 2. There was no documented evidence that a Reference Range was verified on two out of two analyzers. 3. There was no documented evidence that precision and accuracy were performed on two out of two analyzers 4. The TP confirmed on 8/223 at 1:15 pm that PS records were not adequate.

D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PT samples were tested for Total Beta-Human chorionic gonadotropin (hCG)) tests in the calendar year 2023. The TP confirmed on 8/2/23 at 1:45 pm that the LD did not ensure PT Total Beta-hCG PT samples were tested.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Endocrinology, Immunology, Rhesus (Rh) factor, and Serology testing performed with the American Association of Bioanalysts (AAB) in the calendar year 2021, 2022 and 2023 the findings include; 1) There was no documented evident that the LD reviewed PT. 2) The TP confirmed on 8/2/23 at 2:30 pm that the AAB PT results were not reviewed.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to have appropriate education and training documentation on all TP performing laboratory testing on the date of survey. The findings include: 1. The laboratory did not have education records for two out of two TP listed on the CMS form 209. 2. There was no documented evidence that two out of two TP were trained to perform Total Beta-Human chorionic gonadotropin (hCG) testing performed on the Abbott i-Stat analyzer. 2. The TP confirmed on 8/2/23 at 1:40 pm the above records were not on file.